

REMARKS

Claims 23, 26-42 and 46 remain pending in this application. Claims 43-45 have been canceled. Claims 23, 28-30, 32-33, 35-36, 38-39, 42 and 46 are currently amended as to matters of form and to further clarify the intended subject matter. No new matter has been added.

Applicants submit that this Amendment After Final Rejection at least places this application in better form for appeal. Applicants respectfully submit that this Amendment should only require a cursory review because the claim amendments do not add any new features and do not alter the scope of the claims. Accordingly, entry of the present Amendment, as an earnest attempt to advance prosecution and to reduce the number of issues, is requested under 37 C.F.R. §1.116.

CLAIM REJECTION - 35 USC §103

At page 2, the Office Action maintains the rejection of claims 23, 26, 29-40 and 46 under 35 USC §103(a) as being unpatentable over PhysioLogics (Phosphatidylserine complex with Gingko) in view of BOMBARDELLI (EPA 0275005).

At page 6, the Office Action maintains the rejection of claims 23, 26-41 and 46 under 35 USC §103(a) as being unpatentable over PhysioLogics and BOMBARDELLI, and further in view of LOEW (Wiener medizinische Wochenschrift (1946)).

At page 8, the Office Action maintains the rejection of claims 23, 26, 29-40, 42 and 46 under 35 USC §103(a) as being unpatentable over PhysioLogics and BOMBARDELLI, and further in view of KIM et al. (FASEB Journal, March 2003, Vol. 17, No. 4-5).

Applicants respectfully traverse these rejections and will address them in the following remarks.

The Office takes the position that PhysioLogics teaches a composition comprising phospholipid complex that contains 20% phosphatidylserine and *Ginkgo biloba* extract that is advertised to treat mild memory problems associated with aging. What the Office Action does not recognize, however, is that the PhysioLogics product "Phosphatidylserine Complex with Ginkgo" is not a Ginkgo-phospholipid complex that is the subject matter of the present claims. The PhysioLogics product advertised in the document is merely a mixture of a *Ginkgo biloba* extract and a phospholipid complex, i.e., it is not Ginkgo complexed with phospholipids. This is an important distinction between the composition of the present claims and that of PhysioLogics and other products that may have been available in the prior art. The PhysioLogics product is not a Ginkgo-phospholipid complex as defined in the specification.

The ingredients listed in PhysioLogics includes Neuro-PS™ which is "phospholipid complex from soy lecithin". The phospholipid complex contains phosphatidylserine, phosphatidic acid, phosphatidylinositol, soy phospholipids & glycerides,

phosphatidylcholine and phosphatidylethanolamine. A second separately listed ingredient is *Ginkgo biloba* extract. (See, also document from Neuro PS website (<http://www.neurops.com>) already of record from the previous Amendment.

In distinction from the PhysioLogics composition, the present claims feature administering Ginkgo complexed with phospholipid and/or phosphatidylserine, and not a mixture of phospholipid complex and Ginkgo. As detailed in the specification, the formation of *Ginkgo* phospholipid complexes enables the preparation of new biologically active compositions. They possess physico-chemical and spectroscopic characteristics which are markedly different from those of the original components and as such they can be incorporated as active principals into pharmaceutical formulations. For example, Ginkgo shows a strong affinity for phospholipids, resulting in the generation of bonds which markedly modify the physico-chemical and spectroscopic characteristics of these new molecules (see page 6, lines 22-29).

Applicants unexpectedly found that a *Ginkgo biloba* extract complexed with phosphatidylserine can be used to enhance cognitive function and alleviate mental fatigue significantly above the levels provided by the non-complexed extract (see, page 3, lines 16-20 of the International PCT application). As described in the specification, the Ginkgo-phosphatidylserine complex can be obtained from a reaction of the active ingredients of an extract of Ginkgo with a phospholipid containing 20%

phosphatidylserine (see page 5, lines 10-14). The specification further details the preparation of a complex between the *Ginkgo biloba* and phosphatidylserine (see page 6, lines 14-21).

The specification shows, in the cognitive assessment tests and results, that *Ginkgo biloba* extract complexed with phosphatidylserine has outstanding effectivity compared with other tested species (i.e. non-complexed *Ginkgo* or *Ginkgo*-phosphatidylcholine complex), regarding Quality of Memory, Picture Recognition Accuracy, Speed of Memory, Timed Memory Tasks, and other tasks concerning attention (see page 16, line 16 to page 29, line 5, and Figures 1-6). Further support for the unexpectedly superior results of a *Ginkgo*-phosphatidylserine complex was provided in the Rule 132 Declaration of Ezio Bombardelli, already of record. See, Amendment dated May 29, 2009.

BOMBARDELLI describes compositions combining flavonoids with phospholipids. The compositions reportedly have high lipophilia and improved bioavailability as compared with free (not complexed) flavonoids. The compositions are designed for use in cosmetic and other topical compositions. BOMBARDELLI fails to teach or suggest, however, that flavonoids would have any effect on the enhancing cognitive function or alleviating mental fatigue, or for improving memory speed and memory quality, or for treating any disease related to reduced cognitive function and increased mental fatigue, which is the featured subject

matter of the present claims. Furthermore, BOMBARDELLI fails to recognize that a *Ginkgo biloba* extract complexed with phosphatidylserine has significant effects above the non-complexed extract.

LOEW describes additional details regarding the components of a Ginkgo extract such as bilobalide and terpene lactones, as well as additional disclosure regarding acetylcholinesterase inhibitors in treating dementia. Like BOMBARDELLI, however, LOEW also fails to teach or suggest the unexpected results of a Ginkgo-phospholipid complex in a method for enhancing cognitive function and alleviating mental fatigue, or any of the other methods recited in the present claims.

KIM describes the health benefits from botanicals such as grape seed extract due to the anti-oxidant activity of polyphenols and proanthocyanidins. The Office Action relies on KIM for teaching the incorporation of grape seed extract in the PhysioLogics composition for the enhancement of cognitive function. Again, KIM, like LOEW and BOMBARDELLI, fails to teach or suggest the unexpected results of a Ginkgo-phospholipid complex.

For at least these reasons, PHYSIOLOGICS, BOMBARDELLI, LOEW and/or KIM, in any combination, fails to teach or suggest, and would not have rendered obvious the method of claim 23, claim 35, claim 36, and all of claims 26-34, 37-42, and 46 depending thereon. Claims 24 and 25 have been canceled. Thus, Applicants

respectfully request reconsideration and withdrawal of this rejection.

CONCLUSION

Entry of the above amendments is earnestly solicited. Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future submissions, to charge any deficiency or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON

/H. James Voeller/
H. James Voeller, Reg. No. 48,015
209 Madison Street, Suite 500
Alexandria, VA 22314
Telephone (703) 521-2297
Telefax (703) 685-0573
(703) 979-4709

HJV/jr